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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,319	01/31/2001	Richard A. Gambale	B0410/7269D1	2488

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EXAMINER

KENNEDY, SHARON E

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 04/01/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/774,319

Applicant(s)

Gambale et al.

Examiner

Sharon Kennedy

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 7, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20, 22, 24-27, and 29 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20, 22, 24-27, and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12 6) ☐ Other:

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

Double Patenting

2. Claims 20, 22, 24, 25-27 and 29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-20, 24-29, especially claim 13, of copending Application No. 09/299,795. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 13 requires a step of manipulating tissue to initiate fibrin growth within the tissue. This feature is described, for example, on page 15 of that specification, which describes that "irritating" the tissue is beneficial to promote growth. The claimed "irritation" is seen to be the same as "stressing" the tissues, as claimed in the present application. Regarding the remaining claims, although stressing the tissue is not mentioned in the claims, page 4, lines 25+ states that during implantation, the tissue is inherently initiated by injury or aggravation of the tissue. Further, the claims of '795 also require a fibrin promoting substance associated with the implant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 20, 22, 24, 25-27 and 29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24-32, 34, 36, 37, 39 of copending Application No. 09/328,808. Although the conflicting claims are not

identical, they are not patentably distinct from each other because the claims of '808 are directed to a method of implanting an angiogenic material. Although stressing the tissue is not mentioned in the claims, page 4, lines 25+ states that during implantation, tissue growth is inherently initiated by injury or aggravation of the tissue. This overlaps the present claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 20, 22, 24, 25-27 and 29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-13 of copending Application No. 09/368,119. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '119 are directed to a method of implanting an angiogenic material. Although stressing the tissue is not mentioned in the claims, page 5, lines 17+ states that during implantation, the tissue growth is inherently initiated by injury or aggravation of the tissue. This overlaps the present claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 20, 22, 24, 25-27 and 29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16, 18 of copending Application No. 09/990,644. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '664 are directed to a method of

implanting an angiogenic material. Although stressing the tissue is not mentioned in the claims, page 4, paragraph 12 states that during implantation, tissue growth is inherently initiated by injury or aggravation of the tissue. This overlaps the present claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Further Comments Regarding Double Patenting

6. The claims are not obvious in view of the claims set forth in 09/073,118 because those claims are article claims.
7. The claims are not obvious in view of the claims set forth in 09/159,834 because those claims are article claims.
8. The claims are not obvious in view of the claims set forth in 09/162,547 because those claims are article claims.
9. The claims are not obvious in view of the claims set forth in 09/211,332 because those claims are article claims.
10. The claims are not obvious in view of the claims set forth in 09/743,695 because those method claims do not require associating an angiogenic substance with the implant.
11. The claims are not obvious in view of the claims set forth in 09/743,726 because those method claims do not require associating an angiogenic substance with the implant.
12. The claims are not obvious in view of the claims set forth in 09/888,757 because those claims are article claims.

13. The claims are not obvious in view of the claims set forth in 10/048,205 because those claims are article claims or method of making the article
14. The claims are not obvious in view of the claims set forth in 10/048,694 because the method claims do not require associating an angiogenic substance with the implant, rather, the claims are directed to an implant having a matrix carrying a therapeutic agent.
15. The claims are not obvious in view of the claims set forth in 6,248,112 because those method claims do not require associating an angiogenic substance with the implant.
16. The claims are not obvious in view of the claims set forth in 6,277,082 because those method claims (claim 29+) do not require associating an angiogenic substance with the implant, rather, they are directed to identifying ischemic tissue and monitoring the tissue after treatment.
17. The claims are not obvious in view of the claims set forth in 6,432,126 because those claims are article claims.
18. The claims are not obvious in view of the claims set forth in 6,447,522 because those method claims (claims 8, 12) do not require associating an angiogenic substance with the implant, rather, they are directed to identifying ischemic tissue and monitoring the tissue after treatment, or to a method of using a specific implantation device.

Allowable Subject Matter

19. Claims 20, 22, 24-27 and 29 would allowed if terminal disclaimers as set forth above were filed.

20. The following is a statement of reasons for the indication of allowable subject matter: The newly cited patents to Crittenden '324 and Ahern et al., '418 do not say anything about inserting an implant and orienting the implant in the tissue to place the tissue in stress, which promotes angiogenesis. Accordingly, the claims would be allowable if terminal disclaimers were filed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Kennedy whose telephone number is (703) 305-0154.

March 27, 2003


Sharon Kennedy
Primary Examiner